K100711

510(k) Summary

DATE: 3/10/2010

JUN - 9 2010

510(k) Submitter:
ENCISION INC.
6797 Winchester Circle
Boulder, CO 80301 USA
Establishment Registration: 1722040

Contact Person:
Judith V. King, VP Regulatory Affairs and Quality Assurance
Phone: 303-339-6917
Fax: 303-444-2693
e-mail: jking@encision.com

Device Name: Suction Irrigation Electrodes and Adapters

Common name: Device, Electrosurgical, Cutting and Coagulation and Accessories

Classification: CFR Section: 878.4400

Class: II

Product Code: GEI

Predicate Devices:

Trade, Proprietary or Model Name	Manufacturer	510(k)
Model ES1000 series Monopolar Laparoscopic Electrodes with Electroshield	Electroscope, Inc. (now Encision Inc.)	K912780
Nezhat-Dorsey™ Reusable Electrosurgical Attachments	Davol Inc.	K003674
StrykeFlow Electrocautery Probes	Stryker Endoscopy	K963765
Opti4 Laparoscopic Handset and Hollow Electrodes	Covidien (was Valleylab Inc.)	K964175
Universal Plus Multifunction Instrument Control Handles and Laparoscopic Electrodes with Suction Irrigation Lumen	ConMed Corp.	K973890

Reason for 510(k) Submission:
Accumulated changes in design and materials of the Suction Irrigation Electrodes and Adapters raised new issues of safety and efficacy that required testing to confirm the devices were substantially equivalent to the original Encision device and/or predicate devices in commercial distribution. The original 510(k) submission did not have an explicit indications for use statement. Wording based on the original submission and predicate devices is provided.

Description of Device:
The Suction Irrigation Electrodes and Adapters combine AEM shielding technology with suction and irrigation of fluids during laparoscopic electrosurgery to cut and coagulate tissue. The electrodes connect to a compatible electrosurgical generator via an adapter on the ENCISION AEM Monitor.

The AEM Monitoring System, with compatible electrosurgical instruments, is designed to minimize the likelihood of stray energy injuries caused by active insulation failure or capacitive coupling. The monitor does this by shutting down the ESU when excessive current is returned via the shield circuit which extends to near the tip of the electrode.

The electrode has a stainless electrode tip welded onto the distal ID of the active tube. The active tube acts as the suction and irrigation path. The tube assembly has primary and secondary insulation layers which separate the inner active tube from the outer shield tube.

The device has a molded body that interfaces with the 3rd party trumpet valves or luer valves via the appropriate adapter. The Adapters (sold separately) are attached to the body of the electrode to make a compatible connection with selected suppliers of trumpet valve/tube sets. There is an electrical connector on the body capable of accepting Encision AEM cords, which carry the active and AEM shield conductors.

The electrode has various fixed tips at the distal end for surgical manipulation and delivery of electrosurgical energy to the patient. All tip styles are insulated from the end of the active tube to the working portion of the tip.

There is a sliding sheath outside of the tube assembly. The sheath in the extended position minimizes risk of injury to tissue from tips when the electrode is inserted into a trocar cannula or reoriented. Holes in the distal end of the tube facilitate suction when the sheath is extended. When the sheath is retracted the electrode tip is exposed for delivery of electrosurgical energy. The sheath can be locked into place in the extended position, and has tactile stops in both the extended and retracted positions. The sheath is required for full protection from stray energy.

Indications for Use:

Encision's Suction Irrigation Electrodes and Adapters are intended for evacuation of body fluids and to cut and coagulate tissue through a trocar cannula for various general surgical laparoscopic procedures.

Contraindications:

These instruments are not intended for use when laparoscopic electrosurgical techniques are contraindicated.

These instruments have not been shown to be effective for tubal sterilization procedures, and should not be used for these procedures.

Technological Characteristics:

The Encision Suction Irrigation Electrodes and Adapters incorporate the same technological characteristics as the predicate devices for delivery of the ESU high frequency current, consisting of insulated conductors and shafts with appropriately shaped tips for electrosurgery.

Like the Encision predicate device, the electrodes include an additional AEM shielding function which diverts stray energy from the shaft of the instrument and is monitored by the Encision AEM Monitor.

Non-clinical Performance Testing:

Performance of the devices' AEM technology, delivery of electrosurgical energy, and suction/irrigation flow has been verified by bench testing.

Performance Characteristic	**Test Description and Criteria**	**Suction Irrigation Electrode Results**
Continuity	Continuity between active connector and tip of electrode is to be 4 Ohms maximum.	The device was found to have an active circuit resistance $\leq$ 1.618 ohms using a 95% confidence interval with 99% reliability. Pass
	Continuity between shield	The device was found to have a shield circuit

Performance Characteristic	Test Description and Criteria	Suction Irrigation Electrode Results
	connector and distal end of shield tube is to be 2 Ohms maximum.	resistance ≤ 0.830 ohms for a 95% confidence interval with 99% reliability. Pass
Capacitance	Capacitance between active connector and shield connector is 130 pF maximum @ 100 kHz.	The device was found to have a capacitance ≤ 121.49 pF @ 100 kHz using a 95% confidence interval with 95% reliability. Pass
Energy Transmission	The device must transmit the full range of HF energy, from 30 to 60 watts of power in all modes from any approved ESU with less than 10% change in voltage.	The device was subjected to all 7 modes on the Conmed System 5000 ESU (4 cut modes, 3 coag modes). For every mode, at each of the 3 different power settings, the device transmitted the full range of high frequency energy with less than 10% change in voltage. Pass
Flow	Flow rate from the proximal to distal end of the lumen must be a minimum of 580 ml/min when tested with a fluid head height of 57".	The flow rate was found to be greater than 689.7 mL/min using a 95% confidence interval with 95% reliability. Pass

The device meets applicable industry and international standards for electrosurgical accessories.

Standard	Purpose	Summary of Results
IEC 60601-2-2:2006, Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment. (This standard is primarily applicable to electrosurgical generators, but there are clauses applicable to accessories.)	Safety	Satisfactory results for all applicable clauses
IEC 60601-1:1988, with amendments, Medical Electrical Equipment – Part 1: General Requirements for Safety. (Applicable as referenced by the high frequency surgical equipment standard.)	Safety	Satisfactory results for all applicable clauses
AAMI ANSI/ISO 10993-1:2003, Biological evaluation of medical devices - Part 1: Evaluation and testing.	Biocompatibility	Tests selected for limited contact external communicating device to tissue
AAMI/ANSI/ISO 10993-5:1999, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.	Biocompatibility	Non-cytotoxic
AAMI/ANSI/ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and sensitization.	Biocompatibility	Non-irritating, non-sensitizing
AAMI/ANSI/ISO 10993-11:2006, Biological evaluation of medical devices -Part 11: Tests for systemic toxicity.	Biocompatibility	Non-toxic
AAMI/ANSI/ISO 17665-1:2006, Sterilization of healthcare products – Moist heat – Part 1: Requirements for development, validation, and	Sterilization	Recommended Cleaning Method and Moist Heat Sterilization for 10^{-6} SAL

routine control of a sterilization process for medical devices.		was validated

Conclusions:

The performance data for continuity, capacitance, and energy transmission is equivalent to the electrosurgical performance and AEM technology of the Encision predicate device. The performance data for flow rate is within the range of flow rates for the other predicate suction irrigation devices. This demonstrates that the Encision Reusable Suction Irrigation Electrodes and Adapters substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Encision, Inc.
% Intertek Testing Services NA, Inc.
Mr. Jason M. Goss
2307 E. Aurora Road Unit B7
Twinsburg, OH 44087

JUN - 9 2010

Re: K100711
Trade/Device Name: Suction Irrigation Electrodes and Adapters
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 11, 2010
Received: March 12, 2010

Dear Mr. Goss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Names:
Suction Irrigation Electrodes and Adapters

Indications for Use:
Encision's Suction Irrigation Electrodes and Adapters are intended for evacuation of body fluids and to cut and coagulate tissue through a trocar cannula for various general surgical laparoscopic procedures.

Prescription Use ___X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C).....

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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